

REMARKS

Claims 1-42 and 67-70 are pending. No amendments to the claims have been presented in the present response.

I. Objections to the Specification

The Examiner notes that the previously submitted amendment to the specification has not been entered and is objected to because allegedly “the formula at the bottom of the [first] page [of the amendment] has been transposed with the sentence appearing directly above it.” Office Action at page 2. Applicants have corrected the transposed sentences. In light of these amendments, Applicant respectfully requests withdrawal of the objection to the specification and entry of the amendment to the specification.

II. Non-Statutory Double Patenting Rejection

Claims 1-42 and 67-70 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 13, 30-37 and 39 of copending Application No. 09/648,446. Applicants note that the rejection is provisional because no allegedly conflicting claims have been patented. Upon an indication of allowable subject matter, a terminal disclaimer with regard to any issued claims in the ‘126 Application will be filed. Applicants respectfully request that the rejection be held in abeyance until allowable subject matter is indicated.

III. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 67 and 69 stand rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action at page 3. Withdrawal of these rejections is respectfully requested for at least the reasons which follow.

Claims 67 and 69 are allegedly indefinite because “[I]t is unclear from the construction of the claim what is excluded from the composition since it both comprises a polymeric agent to which other compounds may be added and consists essentially of batimastat” *Id.* Applicants respectfully disagree. Initially, the Examiner has provided no support for the proposition that a

composition cannot comprise one component and consist essentially of a second component. The skilled artisan is well aware of the meanings of transition words and phrases such as “comprising” and “consisting essentially of.”

Moreover, it is submitted that the claims are definite when read in light of the specification. *See, e.g.*, specification at page 8, line 6 through page 9, line 8 and page 12, line 3 through page 16, line 2. From such disclosure, the skilled artisan would readily understand a composition that comprises a polymeric suspension agent and consists essentially of about 0.001 to about 3 percent, by weight, of said batimastat compound.

Accordingly, it is submitted that the claims comply with 35 U.S.C. § 112, second paragraph, and withdrawal of this rejection is respectfully requested.

VII. Rejections Under 35 U.S.C. § 102

Claims 7-12, 14, 23-30, 32, 38-42, 69 and 70 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,767,153 (hereinafter “the ‘153 Patent”).

Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987). However, a prior art reference may anticipate a claim without expressly disclosing a feature of the claimed invention if that missing feature is necessarily present, or inherent, in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). In this regard, “the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990); M.P.E.P. § 2112 (emphasis in original); see also *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1351 (Fed. Cir. 2002).

In support of this rejection, the Examiner asserts that because “everyone is susceptible to developing retinal neovascularization by developing the diseases of the retina and/or traumatic ocular insults as described on page 1 of the instant specification, ... the result of the one method step would be the same” as that disclosed in the ‘153 Patent. Applicants respectfully disagree.

The Examiner has not shown that the result of the methods of the '153 Patent necessarily prevent retinal neovascularization. The Examiner appears to confuse the concepts of a mammal possibly developing a disease or condition which could lead to the development of retinal neovascularization with a mammal that is susceptible of developing retinal neovascularization as the result of having such a disease or condition. Treating a random subject with such a composition who never develops a disease or condition associated with the manifestation of retinal neovascularization would not necessarily result in the prevention of such retinal neovascularization. Whatever else the '153 Patent discloses, it does not teach or suggest the prevention of retinal neovascularization in a mammal susceptible to developing retinal neovascularization. The Examiner has provided no support for the assumption that all mammals are susceptible to developing retinal neovascularization. As such, the '153 Patent does not anticipate the present claims.

For at least the aforementioned reasons, it is submitted that claims 7-12, 14, 23-30, 32, 38-42, 69 and 70 are patentable over the '153 Patent, and reconsideration and withdrawal of this rejection is respectfully requested.

VIII. Rejection under 35 U.S.C. § 103(a)

Claims 1-42 and 67-70 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,767,153 (the '153 Patent) in view of WO 97/41844 (the '844 publication). Office Action at page 5. Applicants respectfully disagree and traverse for at least the reasons that follow.

While the Examiner acknowledges that the '153 Patent fails to disclose the "use of the composition of polycarbophil and batimastat for the treatment of retinal neovascularization," the Examiner attempts to remedy this by arguing that the '844 publication "discloses that batimastat is an angiostatic agent (Table 1) and as such is effective in compositions for the treatment of diseases where neovascularization arises." Office Action at page 5.

Applicants respectfully disagree with the Examiner's characterization of the art. By way of example, the Examiner asserts that "batimastat is known to be useful to treat retinal

neovascularization as taught in '844." Office Action, at page 6. In this regard, the '844 publication nowhere mentions the treatment or prevention of retinal neovascularization by administration of a batimastat other than, at best, in a putative combination treatment. Rather, the '844 publication discusses the use of combination of numerous possible known angiostatic compounds. Furthermore, batimastat is one of a very long list of possible known angiostatic compounds listed for use in such combination therapies. In fact, the '844 publication contemplates the combined therapeutic use of angiostatic compounds, together with other angiostatic compounds, indicating that compositions comprising batimastat alone are insufficient to treat or prevent retinal neovascularization. As such, the '844 publication fails to provide any disclosure or teaching, or even suggestion that retinal neovascularization can be treated or prevented by topically administering to the eye a composition capable of delivering a therapeutically effective amount of a batimastat compound.

Nonetheless, whatever else '844 does disclose, it does not disclose a composition capable of delivering a therapeutically effective amount of a batimastat compound, much less the ability of batimastat compounds to treat retinal neovascularization. The '153 Patent does not teach, disclose, or suggest the use or ability of such compositions to treat or prevent retinal neovascularization.

In a proper obviousness determination, the changes from the prior art must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the claimed invention. *See In re Chu*, 36 U.S.P.Q.2d 1089, 1094 (Fed. Cir. 1995). This includes what could be characterized as simple changes. *See, e.g., In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984) (Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.).

As such, it is respectfully submitted that the Examiner's conclusion of obviousness is based on improper reasoning and a mischaracterization of the art. No suggestion to modify the cited references has been found in the cited references or pointed out to Applicant from the

general knowledge of one of ordinary skill in the art. For at least these reasons, the Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness, as required by 35 U.S.C. § 103.

In sum, the prior art of record provides no suggestion or motivation to one of ordinary skill in the art to modify the teachings of the '153 Patent with the teachings of the '844 publication to arrive at the present invention. The cited references do not disclose or suggest methods for treating or preventing retinal neovascularization in a mammal susceptible to developing retinal neovascularization by topically administering to the eye a composition capable of delivering a therapeutically effective amount of a batimastat compound. As such, the cited references do not render the present claims obvious.¹

For at least the foregoing reasons, the Examiner's characterization of the art is traversed, and it is respectfully submitted that all of the pending claims are non-obvious over the prior art of record. As such, reconsideration and withdrawal of this rejection is respectfully requested.

¹ With respect to claim 68, the Examiner cites to several cases regarding the use of the transition phrase "consisting essentially of." Office Action at pages 8-9. For the reasons stated, the cited references do not render the claims reciting "comprising" obvious, nor do the references render the claims reciting "consisting essentially of" obvious.

Conclusion

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5000 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. M. Freed", with a long horizontal line extending to the right.

Joel M. Freed (Reg. No. 25,101)
Joseph W. Ricigliano (Reg. Agent No. 48,511)
Thomas E. Holsten (Reg. No. 46,098)

Date: February 8, 2005

ARNOLD & PORTER LLP

555 Twelfth Street, NW
Washington, D.C. 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile